IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gina FISCHER et al.
Title:	MORPHINE CONTROLLED RELEASE SYSTEM
Appl. No.:	10/550,453
International Filing Date:	3/26/2004
371(c) Date:	08/18/2006
Examiner:	Sasan, Aradhana
Art Unit:	1615
Confirmation Number:	3166

AMENDMENT AND REPLY UNDER 37 C.F.R. § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Amendment and Reply is responsive to the Non-Final Office Action dated November 10, 2009, concerning the above-referenced patent application. This Amendment is being timely filed on or before the due date of February 10, 2010.

Amendments to the Specification are reflected in the replacement paragraphs which begin on page 3 of this document.

Amendments to the Claims are reflected in the listing of claims which begins on page 5 of this document.

Remarks/Arguments begin on page 8 of this document.

Please amend the application as follows:

Amendments to Specification

Please amend the paragraph bridging pages 2-3 of the application as filed, as follows:

Many controlled release products on the market suffers from the lack of a true controlled release. In fact, ~~Dolcontin®~~ DOLCONTIN®, which covers most of the market for sustained morphine, results in a plasma profile rather similar with an immediate release dosage formulation only with a slight decrease in the initial burst. During the repeated administration, the plasma concentration with this product will necessarily exhibit the undesired peaks and troughs as is also shown in FIG. 18 comparing the commercial twice daily MS ~~Contin~~ CONTIN® with the commercial available ~~Kadian~~ KADIAN® multiple pellet formulation, both demonstrating a fluctuation during the day where the minimum concentration is less than half of the maximal concentration for each of the two formulations. Such degree of fluctuation in concentration during the dosing interval may be avoided with the opioid composition according to the present invention.

Please amend line 28 on page 19 of the application as filed, as follows:

Poloxamers are sold under the trademark ~~Pluronic®~~ PLURONIC® or ~~Lutrol®~~ LUTROL®.

Please amend paragraphs between lines 1-10 on page 44 of the application as filed, as follows:

FIG. 17 shows a linear XY plot of mean plasma Morphine concentrations versus time curves for Study 3 following a single dose of 1 x 30 mg ~~Morphine Sulphate Egalete®~~ EGALET® Morphine Sulphate controlled release Test Formulation (A), Batch 03-0062-066, shape Cone 5 fed and fasted), or a single dose of 1 x 30 mg MST ~~Continus®~~ CONTINUS® tablet (Reference Formulation (B)).

FIG. 18 shows dose normalized mean steady plasma morphine concentration from commercial available ~~Kadian®~~ KADIAN® (once a day) and an equivalent dose of a 12-hour, controlled-release morphine tablet given twice a day. Plasma concentrations are normalized